

PACKAGE LEAFLET: Information for the user

FASTGO

Gel – 2.5%

(Ketoprofen)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What FastGo is and what it is used for
2. What you need to know before you use FastGo
3. How to use FastGo
4. Possible side effects
5. How to store FastGo
6. Other information

1. WHAT FASTGO IS AND WHAT IT IS USED FOR

FastGo gel contains the active substance ketoprofen. Ketoprofen, a propionic acid derivative, is a non-steroidal anti-inflammatory drug with a strong analgesic action.

FastGo is used in:

- inflammatory or traumatic diseases of joints, tendons, ligaments and muscles;
- musculo-skeletal disorders, such as spondylitis, osteoarthritis, and rheumatoid arthritis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FASTGO

Do not use FastGo if you are hypersensitive to:

- ketoprofen, tiaprofenic acid, fenofibrate, UV blockers or perfumes;
- any of the excipients of the drug;
- aspirin or other NSAIDs.

Stop using FastGo immediately if you experience any skin reaction including cutaneous reactions after co-application of octocrylene containing products (octocrylene is one of the excipients of several cosmetic and hygiene products such as: shampoo, after-shave, shower and bath-gels, skin creams, lipsticks, anti-ageing creams, make up removers, hair sprays, used in order to delay photodegradation).

Do not use FastGo if you have a history of any photosensitivity reaction.

Do not expose treated areas to sunlight or UV light from solarium during treatment and in the two weeks following its discontinuation.

Warnings and precautions

Ask your doctor before using FastGo because hypersensitivity cases may appear if drugs are used topically. In these cases treatment should be interrupted and according to the doctor advice it can be replaced with another treatment.

The use of large amounts of ketoprofen gel may give systemic effects including hypersensitivity and asthma (cases of renal disease have been reported).

Talk to your pharmacist or doctor if you have an infection – please see heading “Infections” below.

The exposure to the sun (even hazy) or to UVA of areas in touch with FastGo can induce potentially serious cutaneous reactions (photosensitisation). Therefore it is necessary to:

- protect treated areas by wearing clothing during the treatment and for two weeks after its discontinuation to avoid any risk of photosensitization;
- wash your hands thoroughly after each application of FastGo.

Tight clothing should not be used in the area where the gel is used.

Avoid contact with eyes, mucous membranes, with inflamed skin or wounded skin.

Ask your doctor before using FastGo if you have heart, liver or kidney problems.

This drug is not usually used in children.

Infections

FastGo may hide signs of infections such as fever and pain. It is therefore possible that FastGo may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Other medicines and FastGo

Tell your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, e.g. oral anticoagulants and including those medicines obtained without prescription, especially those for pain relief, such as aspirin or other NSAIDs or methotrexate used for the treatment of some types of cancer or psoriasis. Inform your doctor that you are using FastGo if you are given any other medicine during treatment. These drugs may affect or be affected from FastGo. You may need to use different quantities of the drug or take other drugs. Your doctor or pharmacist will advise you.

Pregnancy and breastfeeding

Do not use if you are in the last 3 months of pregnancy. It may affect your baby.

Do not use this medicine if you are breastfeeding. This is because small amounts may pass into mothers' milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

FastGo has no effect on driving and using machinery.

Important information about some of the excipients of FastGo

FastGo contains:

- fragrance allergens, which may cause allergic reactions;
- 0.41 g alcohol (ethanol) in each 1 g gel, which may cause burning sensation on damaged skin.

3. HOW TO USE FASTGO

Always use FastGo exactly as your doctor or pharmacist has told you or as it is written in the package leaflet. Check with your doctor or pharmacist if you are not sure about the dose you should use and when you should use it.

Apply 2 – 4 times daily in the affected area, massaging it gently. Treatment may continue up to 7 days. Do not apply more than 15 g of gel (equivalent to approximately 35 cm strip) in any one day.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Wash your hands before use and immediately after use.

Once applied, do not cover the area with a dressing or plaster.

If you use more FastGo than you should

If you use more FastGo than you should, or if your child has used it by mistake, contact your doctor, the hospital or the emergency room so that you will be advised for the possible risk and the actions to take.

Topical application of large amounts can result in systemic effects, including hypersensitivity and asthma (renal disease has also been reported).

If you forget to use FastGo

If you forget to use FastGo, use it as soon as you remember, but do not apply excessive amounts.

If you have any further questions, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Ketoprofen gel may cause: local skin reactions which may spread beyond the area of application, burning sensation, hypersensitivity reactions in extended use, allergy skin reactions, severe skin reactions during an exposure to sunlight. Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely. Also a serious allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing (anaphylactic shock) or flu-like symptoms at the same time, such as fever, chills or aching muscles may occur.

Stop using FastGo immediately and see your doctor or go to the hospital straight away if you notice the above side effects.

Other undesirable effects depend on the transdermic spreading of the active ingredient and hence on the amount of gel applied, on the surface involved, on the degree of intactness of the skin, on the duration of treatment and on the use of occlusive bandaging.

Tell your doctor if you notice any of the following side effects listed according to frequency:

Uncommon side effects (may affect up to 1 in 100 people):

Erythema, pruritus, eczema.

Rare side effects (may affect up to 1 in 1,000 people):

Photosensitivity reactions, dermatitis bullous, urticaria.

Very rare side effects (may affect up to 1 in 10,000 people):

Renal failure or deterioration of renal failure.

Not known (frequency cannot be estimated from the available data):

Anaphylactic reaction, hypersensitivity reactions, peptic ulcer, gastrointestinal bleeding, diarrhea, contact dermatitis, burning sensation, angioedema, wound complications in patients with increased vulnerability to infection, eosinophilia, fever, vasculitis.

5. HOW TO STORE FASTGO

Keep this medicine out of the sight and reach of children!

Do not use FastGo after the expiry date which is stated on the package.

Do not store above 25°C!

Store in the original package!

Protect from fire!

Read the package leaflet before use.

6. OTHER INFORMATION

What FastGo 2.5% gel contains

The active substance is ketoprofen.

1 g gel contains 25 mg ketoprofen.

The other ingredients are: carbomer, disodium-EDTA, ethanol, triethanolamine, lavender oil, purified water.

Content of the pack

Carton box with one aluminium tube of 50 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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